PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference APL03-03PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/CA2004/002001	International filing date *(day/month/year)* 19 November 2004 (19.11.2004)	Priority date *(day/month/year)* 21 November 2003 (21.11.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant AVENTIS PASTEUR LIMITED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 22 May 2006 (22.05.2006)
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 15 March 2005 (15-03-2005)

Applicant's or agent's file reference APL-03-03-PCT	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/CA2004/002001	International filing date *(day/month/year)* 19 November 2004 (19-11-2004)	Priority date *(day/month/year)* 21 November 2003 (21-11-2003)

International Patent Classification (IPC) or both national classification and IPC
IPC7 C12N 15/31, A61K 39/118, A61K 31/7088, A61P 31/04, C07H 21/00, C07K 14/295, C07K 16/12, C12P 21/02, A61K 38/16

Applicant
AVENTIS PASTEUR LIMITED ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[X]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office *Place du Portage I, C114 - 1st Floor, Box PCT* *50 Victoria Street* *Gatineau, Quebec K1A 0C9* Facsimile No: 001(819)953-2476	Kristoffer Wilde (819) 953-0551

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language which it was filed, unless otherwise indicated under this item.

   [ ] This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      [X] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [X] in written format

      [X] in computer readable form

   c. time of filing/furnishing

      [X] contained in the international application as filed.

      [ ] filed together with the international application in computer readable form.

      [X] furnished subsequently to this Authority for the purposes of search.

3. [X] In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/002001

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim Nos. 16-19 and 38

because:

[X] the said international application, or the said claim Nos. 16-19 and 38 relate to the following subject matter which does not require an international preliminary examination *(specify)* :

Although claims 16-19 and 38 are directed to methods of the human/animal body which this Authority is not obliged to search under Rule 39. (iv) of the PCT, the search has been carried out based on the alleged effects of the compounds referred to therein.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)* :

[ ] the claims, or said claim Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

[ ] no international search report has been established for said claim Nos. _____.

[ ] the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that :

the written form [ ] has not been furnished

[ ] does not comply with the standard

the computer readable form [ ] has not been furnished

[ ] does not comply with the standard

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/002001

Box No. IV Lack of unity of invention

1. [ ] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has :

   [ ] paid additional fees

   [ ] paid additional fees under protest

   [ ] not paid additional fees

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   [X] complied with

   [ ] not complied with for the following reasons :

4. Consequently, this opinion has been established in respect of the following parts of the international application :

   [X] all parts

   [ ] the parts relating to claim Nos. _____

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CA2004/002001

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	none	YES
	Claims	1-38	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-38	NO
Industrial applicability (IA)	Claims	1-38	YES
	Claims	none	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: WO 03 049762 A2 (CHIRON SPA)
19 June 2003 (2003-06-19)

D2: WO 99 28475 C2 (GENSET)
26 Aug 1999 (1999-08-26)

D3: STEPHENS RS ET AL: "Genome Sequence of an Obligate Intracellular Pathogen of Humans: *Chlamydia trachomatis*" SCIENCE, Vol. 282, 23 October 1998 (1998-10-23), pages 754-759

D4: READ TD ET AL: "Genome Sequences of *Chlamydia trachomatis* MoPn and *Chlamydia pneumoniae* AR39" NUCLEIC ACIDS RESEARCH, Vol. 28, No. 6, 15 March 2000 (2000-03-15), pages 1397-1406

Novelty and Inventive Step - Articles 33(2) and 33(3) PCT

The problem to be solved by the instant application is the provision of a nucleic acid comprising a Mgp002 gene or a truncated form thereof derived from *Chlamydia trachomatis* or *Chlamydia muridarum* to generate a protective immune response to *Chlamydia*.

D1 discloses a number of *Chlamydia trachomatis* protein sequences suitable for vaccine production, vaccine development, and diagnosis purposes. Namely, OMP (SEQ ID No:27), which has 100% identity with the Mgp002 protein from *Chlamydia trachomatis* (SEQ ID No:4 of the instant application) and the nucleic acid sequence (SEQ ID No:28) which has 100% identity with the Mgp002 gene from *Chlamydia trachomatis* (SEQ ID No:3 of the instant application). SEQ ID No:27 also has 83% identity with the Mgp002 protein from *Chlamydia muridarum* (SEQ ID No:2 of the instant application). Further, D1 discloses host cells (see pages 9-22), pharmaceutical compositions for both the protein and the nucleic acid (see pages 22-31), gene delivery vehicles (see page 25), antibodies (see page 22), primers (see page 34), delivery methods (see page 29) and fusion proteins comprising SEQ ID No:27 (see Example 20). Accordingly, claims 1-38 are considered to be anticipated by D1 and therefore not compliant with Article 33(2) PCT.

Continued in Supplemental Box...

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Claims

Claims 1, 2, 8, 10, 12, 15, 16, 19, 30, 31, 33, 34, and 38 are not compliant with Article 6 PCT. The algorithm used to determine the percent sequence identity has not been specified in the claims.

Claims 17 and 27 depends on their selves and therefore are not compliant with Article 6 PCT.

Claims 21 and 22 are not compliant with Article 6 PCT. The stringent hybridization and wash conditions should be defined to fully define the nucleic acid molecule.

Claim 24, 26 and 28 are not compliant with Article 6 PCT. Said claims refer to the polypeptide of claim 7, however claim 7 is directed to a nucleic acid, not a polypeptide.

Claim 29 is not compliant with Article 6 PCT. Said claim refers to the vaccine according to claim 28 but claim 28 is to a composition, not a vaccine.

Claim 30 is not compliant with Article 6 PCT. A polynucleotide either is or is not homologous. It cannot be 95% homologous.

Description

Applicant refers to *Chlamydia muridium* throughout the instant application, but the designation *Chlamydia muridarum* is used in the prior art. The instant application was examined under the assumption that the designations *Chlamydia muridium* and *Chlamydia muridarum* are interchangeable.

On page 2 of the instant application, applicant refers to WO 01/21803 as disclosing the *C. pneumoniae* Mgp002 gene, but it looks like the *C. pneumoniae* Mgp002 gene was actually disclosed in WO 01/21804. WO 01/21803 discloses a *C. pneumoniae* ADP/ATP translocase, while WO 01/21804 discloses a *C. pneumoniae* outer membrane protein. Accordingly, the description is not compliant with Article 5 PCT.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box No. V:

D2 discloses nucleotide sequences encoding polypeptides of *Chlamydia trachomatis* and vaccine compositions comprising said nucleic acids or vaccine compositions comprising said polypeptides (see pages 74-79). The polypeptide of SEQ ID No:78 (468 aa) disclosed by D2 shares at least 80% identity with the Mgp002 protein from *Chlamydia trachomatis* (SEQ ID No:4 of the instant application). Further, polypeptide of SEQ ID No:78 shares at least 100 consecutive amino acids with SEQ ID No:4 of the instant application (for example, aa 79 to 193 of SEQ ID No:4). Further, host cells, compositions, antibodies, primers and fusion proteins are disclosed. Accordingly, claims 1-38 are considered to be anticipated by D2 and therefore not compliant with Article 33(2) PCT.

D3 discloses the genome sequence of *Chlamydia trachomatis,* which was made available under GenBank accession number AE001273 (see page 754, column 3, paragraph 2). GenBank accession number AE001308 comprises section 35 of AE001273 and encodes a protein (GenBank accession number AAC67945.1) that shares 100% identity with the Mgp002 protein from *Chlamydia trachomatis* (SEQ ID No:4 of the instant application) and 83% identity with the Mgp002 protein from *Chlamydia muridarum* (SEQ ID No:2 of the instant application). Accordingly, claims 1, 2, 3, 23, 30 and 31 are considered to be anticipated by D3 and therefore not compliant with Article 33(2) PCT.

D4 discloses the genome sequence of *Chlamydia trachomatis* MoPn (also known as *Chlamydia muridarum*), which was made available under GenBank accession number AE002160 (see page 1398, last paragraph). GenBank accession number AE002331 comprises section 61 of AE002160 and encodes a protein (GenBank accession number AAF39458.1) that shares 100% identity with the Mgp002 protein from *Chlamydia muridarum* (SEQ ID No:2 of the instant application) and 83% identity with the Mgp002 protein from *Chlamydia trachomatis* (SEQ ID No:4 of the instant application) . Accordingly, claims 1, 2, 3, 23, 30 and 31 are considered to be anticipated by D4 and therefore not compliant with Article 33(2) PCT.

Inventive Step - Article 33(3) PCT

Given the lack of novelty in claims 1-38 according to Article 33(2) PCT in view of D1 or D2, said claims also lack an inventive step in view of Article 33(3) PCT.

Industrial Applicability - Article 33(4) PCT

Claims 1-15 and 20-37 appear to define subject matter that has industrial applicability under Article 33(4) PCT based on the function of the Mgp002 gene or a truncated form thereof derived from *Chlamydia trachomatis* or *Chlamydia muridarum* as an immunogen for protection against disease caused by infection with *Chlamydia.*

Although the methods per se defined in claims 16-19 and 38 relate to subject matter which this Authority is not obliged to examine under Rule 67.1 (iv) of the PCT, the use of the compounds referred to therein for preventing or treating *Chlamydia* infection appears to represent subject matter that has industrial applicability.